| | Application No. | Applicant(s) |
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| Notice of Allowability | 10/075,175 | PEABODY ET AL. |
| | Examiner | Art Unit |
| | Joseph W. Drodge | 1723 |
| The MAILING DATE of this communication appearance All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this applied or other appropriate communication IGHTS. This application is subject to | plication. If not included will be mailed in due course. THIS |
| 1. \boxtimes This communication is responsive to <u>the Amendment filed</u> | on December 24, 2003. | |
| 2. The allowed claim(s) is/are <u>1-64</u> . | | |
| 3. \square The drawings filed on <u>14 February 2002</u> are accepted by the | he Examiner. | |
| 4. ☐ Acknowledgment is made of a claim for foreign priority una) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority do | e been received. e been received in Application No | <u>. </u> |
| International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | complying with the requirements |
| 5. A SUBSTITUTE OATH OR DECLARATION must be subminFORMAL PATENT APPLICATION (PTO-152) which give | | |
| 6. CORRECTED DRAWINGS (as "replacement sheets") mus | st be submitted. | |
| (a) \square including changes required by the Notice of Draftspers | son's Patent Drawing Review (PTO- | 948) attached |
| 1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date | | |
| (b) ☐ including changes required by the attached Examiner' Paper No./Mail Date | s Amendment / Comment or in the C | Office action of |
| Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t | | |
| 7. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT | | |
| | | |
| Attachment(s) 1. ⊠ Notice of References Cited (PTO-892) | 5. Notice of Informal P | atent Application (PTO-152) |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. Interview Summary | |
| 3. Information Disclosure Statements (PTO-1449 or PTO/SB/0 Paper No./Mail Date | Paper No./Mail Dat 08), 7. ⊠ Examiner's Amendr | |
| 4. Examiner's Comment Regarding Requirement for Deposit | 8. 🛛 Examiner's Stateme | ent of Reasons for Allowance |

of Biological Material

9. 🔲 Other _____.

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In claim 1, lines 1-2 of the last clause –operative—has been inserted after "said system sterilization component".

In claim 23, line 23 --, wherein said system controller is operative to control said filter test component to test said sterilization filter assembly after said dialysate has passed through said filter assembly and before said dialysate is delivered to the patient during the peritoneal dialysis—has been inserted after "delivery".

In claim 49, line 7 –after said passing step—has been inserted after "process". In claim 62, line 1 –said—has been inserted after "controls".

Authorization for this examiner's amendment was given in a telephone interview with Cort Flint on February 18, 2004.

The narrowing/clarifying amendments to claims 23 and 49 are supported by the text of the instant Specification at page 12, lines 6-14.

The following is an examiner's statement of reasons for allowance: Independent claim 1 and claims dependent therefrom now distinguish over Peabody et al and Wamsiedler et al, of record, and in view of newly cited Summertown et al patent 6,635,179, in view of recitation in the last clause of the claim concerning "control system... system sterilization component... operative to test... event of filter failure.

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Independent claim 23 and claims dependent therefrom distinguishes over the same prior art in view of "system controller is operative... filter test component... to test...after said dialysate has passed through said filter assembly and beforeperitoneal dialysis". The prior art concerning integrity testing of sterilization filters for both peritoneal dialysis and hemodialysis all teach such integrity testing before passing any dialysate through the filter with a test fluid unrelated to dialysate.

Independent claims 32 and 39 remain distinguished for reasons of record.

Independent claim 49 and claims dependent therefrom distinguish over the forementioned prior art in view of "testing said sterilization filter assembly in realtime during the process after said passing step...prior to delivering said dialysate to the peritoneal cavity".

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is

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703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

February 20, 2004

JOSEPH DRODGE DRIMARY EXAMINER